

### REMARKS

The specification has been amended to insert a formula which covers the three disclosed lignans. This formula demonstrates that the three disclosed lignans are structurally related.

Claims 1 and 7 have been amended to insert the same formula for the three disclosed lignans, again to show the structural relationship of these lignans. Claims 11, 12 and 14 have been amended to correct minor typographical errors. New claims 17 and 19 have been added to claim the lignan as hydroxymatairesinol or a mixture of hydroxymatairesinol and matairesinol. New claims 18 and 20 have been added to claim the lignan as hydroxymatairesinol or a mixture of hydroxymatairesinol and enterolactone.

It is submitted that these amendments do not constitute new matter, and their entry is requested.

In the Office Action mailed 24 March 2003, the Examiner required election of one invention out of a proposed 127 groups. Applicants provisionally elect Group 1, with traverse. Claims 1-6 and 17-18 read on Group 1.

The Examiner contends that the groups are unrelated because the active agents differ with respect to their structure, the diseases differ with respect to their etiology and the treatment differs with respect to the process steps. The Examiner is clearly incorrect in these assertions. As shown by the formula incorporated into the amended claims, the active agents are structurally related. As detailed in the specification and set forth in the claims, the etiology of the diseases is the same, namely, overactivity of phagocytes or lymphocytes. The treatment steps are all the same, i.e., administering the active agent to an individual in need of treatment, i.e., an individual having overactive phagocytes or lymphocytes. Furthermore, the active agents all have the same mode of action, i.e., inhibition of the overactivity of phagocytes or lymphocytes. Thus, it is submitted that the alleged inventions of Groups 1-127 are related.

In addition, the Examiner has shown that the search for each of the alleged groups is identical. The field of search includes only two classes. Class 514, subclass 22, is based on the structure of the active agent, not the disease. Applicants are unable to determine the subject matter


of Class 424, subclass 195.1, since it is not included in the online edition of the *Manual of Classification*. Thus, the search to be conducted for any alleged invention, e.g., for the invention of Group 1, would encompass the subject matter of all of the groups. Furthermore, a method that comprises administering one agent, e.g., hydroxymatairesinol, reads on a method that comprises the administration of this agent in admixture with a second agent, e.g., matairesinol.

Furthermore, there are two criteria for a proper requirement for restriction between patentably distinct inventions: 1) The inventions must be independent or distinct as claimed; and 2) There must be a serious burden on the Examiner if restriction is not required. See MPEP § 803. Examiners must provide reasons and/or examples to support conclusions. For purposes of the initial requirement, a serious burden on the Examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. The field of search and the classification are identical for the alleged 127 groups, and no separate status in the art has been asserted.

Distinctness alone is not enough to require a restriction. There must also be a serious burden upon the examiner. See MPEP § 803. MPEP § 803.02 states that if a search and examination of an entire case can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. It is urged that the burden of examining all of the groups of the present application is not a serious one, especially since the same field of search would be performed for each group and the classification of each group is identical. In addition, the search would be directed to the same activity of the active agents, i.e., the inhibition of overactive phagocytes or lymphocytes, the method of claims 1-6, 17 and 18 and a limitation of claims 7-16, 19 and 20. In fact the acute ischemia-reperfusion injury or chronic condition is caused by overactive phagocytes or lymphocytes as set forth in claims 7-16, 19 and 20. Thus, the search for each of the alleged 127 inventions is identical, and consequently can be made without a serious burden.

For these reasons, Applicants submit that the restriction is improper, and that there would be no undue burden to search all of the claimed subject matter. Thus, it is requested that the restriction requirement be withdrawn, and all of the claims be examined together.

In view of these remarks, it is requested that the Examiner reconsider the restriction requirement and join all the claims for examination, or in the alternative, reformulate the restriction requirement.

RESPECTFULLY SUBMITTED,					
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